IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

AGHI *et al.*

Appl. No. 09/617,116

Filed: July 14, 2000

For: **Folylpolyglutamyl Synthetase Gene Transfer to Enhance Antifolate Drug Sensitivity**

Confirmation No. 5851

Art Unit: 1636

Examiner: Nguyen, Q.

Atty. Docket: 0609.4830001/JAG/KRM

Reply To Restriction Requirement and Requirement for Election Of Species

Commissioner for Patents
Washington, D.C. 20231

Sir:

In reply to the Office Action dated **February 8, 2002** (PTO Prosecution File Wrapper Paper No. 8), requiring an election of one invention to prosecute in the above-referenced patent application and requiring an election of species, Applicants present the following remarks.

Restriction Requirement

Applicants hereby provisionally elect to prosecute the invention of Group I, represented by claims 1-3 and 5-13. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed.

This election is made **with** traverse.

Applicants respectfully submit that the Examiner, in the present Office Action, has not set forth a proper restriction requirement. According to the Manual of Patent Examining Procedure (MPEP), an Examiner, when making a restriction requirement, should identify

each separate subject amongst which restriction is required, and group each claim with its subject. *See* MPEP § 814. That is, each claim that is alleged to encompass an independent and distinct invention should be placed in one, and only one, restriction group. The importance of placing a claim into only one group is emphasized in MPEP § 817 where Examiner's are instructed to "[l]ist claims in each group. Check accuracy of numbering of the claims; *look for same claims in two groups*; and look for omitted claims." (Emphasis added). Thus, in preparing a proper restriction requirement, Examiners are specifically instructed not to place a single claim in more than one restriction group.

Here, the Examiner has made an improper restriction requirement by placing claims 1-3, 5-6, 11 and 13 in *all three* of the restriction groups. This is clearly improper practice under the MPEP. Moreover, the placing of a single claim in more than one group is incongruous with the basic underlying purpose of restriction requirements; that is, the purpose of a restriction requirement is to identify claims that encompass independent and distinct inventions. *See* 37 CFR § 1.142(a). It follows logically, therefore, that a claim cannot be placed in two or more restriction groups as the Examiner has done in the present Office Action.

Additionally, Applicants note that the Examiner has characterized claims 1-3, 5-6, 11 and 13 as "linking claims." *See* Paper No. 8, page 2. As defined in MPEP § 809.03, a "linking claim" is one that is inseparable from the "inventions otherwise divisible," such as a genus claim linking species claims. The MPEP further instructs that "generic or other linking claims should not be associated with any one of the linked inventions since such claims must be examined with any one of the linked inventions that may be elected." *See* MPEP § 814. Thus, if claims 1-3, 5-6, 11 and 13 are indeed "linking claims," as asserted

by the Examiner, then under MPEP § 814, it is improper to associate them with any of the restriction groups.

The Examiner has characterized the restriction groups as follows:

> I. Claims 1-3 and 5-13, drawn to a method for killing neoplastic cells utilizing a vector for gene delivery, wherein said vector comprising a nucleotide molecule encoding FPGS and *said vector for gene delivery is a viral or non-viral vector*, classified in class 514, subclass 44.
>
> II. Claims 1-3, 5-6, 11 and 13, drawn to a method for killing neoplastic cells utilizing a vector for gene delivery, wherein said vector comprising a nucleotide molecule encoding FPGS and *said vector for gene delivery is an endothelial cell*, classified in class 424, subclass 93.2.
>
> III. Claims 1-3, 5-6, 11 and 13, drawn to a method for killing neoplastic cells utilizing a vector for gene delivery, wherein said vector comprising a nucleotide molecule encoding FPGS and *said vector for gene delivery is a macrophage*, classified in class 424, subclass 93.2.

Paper No. 8, page 2 (emphasis added). Applicants note that the italicized language in the quotation above represents limitations that are *not* found in any of the claims except for claim 7 (and claims 8 and 9 which are dependent therefrom), which specifies that said vector for gene delivery is a viral vector, claim 10, which specifies that said vector for gene delivery is non-viral, and claim 11, in which endothelial cell and macrophage are included in a Markush group of vectors. Thus, in an attempt to place the claims into different restriction groups, the Examiner has added limitations that are not included within many of the claims as currently written. For instance, claims 1-3, 5 and 6, which the Examiner has placed in all three restriction groups, contain no limitations as to the vector for gene delivery. Since Applicants have not included these limitations within the claims (except for claims 7-9, 10 and 11, mentioned above), it is improper for the Examiner to read these limitations into the claims for purposes of facilitating the creation of restriction groups.

The Examiner has set forth the following explanation to justify the restriction requirement:

> Methods cited in inventions in I-III which utilize a viral or non-viral vector, an endothelial cell and a macrophage, respectively, lack unity of invention. There is no common substantial structural feature among a viral or non-viral vector with an endothelial cell, or with a macrophage or between an endothelial cell and a macrophage. The methods comprise materially distinct processing steps and require different technical considerations for delivering into neoplastic cells a vector for gene delivery in the forms of viral or non-viral vector or in the form of an endothelial cell or a macrophage, and that they are not required one for the other.

Paper No. 8, pages 3-4. Applicants respectfully traverse these assertions insofar as they relate to the issue of distinctness and/or independence of invention. In addition, Applicants note that the Examiner, in setting forth the above explanation, has assumed that certain claims are limited to either (a) viral or non-viral vector, (b) endothelial cell vector or (c) macrophage vector. As discussed previously, the only claims containing such limitations are claims 7 (and claims dependent therefrom), 10 and 11. Therefore, claims that do not contain limitations as to the nature of the vector for gene delivery should not be placed within the restriction groups as set forth by the Examiner.

In sum, the Examiner has established three restriction groups and has placed claims 1-3, 5, 6, 11 and 13 into *all three* of these groups. The placement of individual claims into multiple restriction groups is improper under MPEP § 814 and is inconsistent with the underlying purpose of restriction practice. Moreover, the Examiner has attempted to facilitate the creation of restriction groups by reading into certain claims limitations regarding the identity of the vector for gene delivery that are not present in the claims as

presently written. This is improper because the Examiner cannot impose claim limitations for purposes of facilitating the creation of restriction groups. In view of the foregoing discussion, Applicants respectfully request that the restriction requirement be reconsidered and withdrawn.

Election of Species Requirements

The Examiner stated that if Group I is elected, Applicants are required under 35 USC § 121 to provide an election of species to one of the following for prosecution on the merits to which the claims shall be restricted: a prokaryotic vector, a cationic liposome, a fusogenic liposome, a DNA-adenovirus conjugate, a DNA-protein complex, a non-viral T7 autogene vector, a starburst polyamidoamine dendrimer, a cationic peptide and a mammalian artificial chromosome. *See* Paper No. 8, page 4.

Accordingly, Applicants hereby provisionally elect the following species: **prokaryotic vector**. Claims 1-3, 5, 6 and 10-13 read on such species. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed.

Applicants assert the right to claim additional species in the event that a generic claim thereto is found to be allowable in accordance with 37 C.F.R. § 1.141(a).

This election of species is made **with** traverse on the ground that the restriction requirement upon which the election of species requirement is based is improper for the reasons set forth above. Applicants further traverse the election of species requirement on the ground that the listed species of non-viral vectors are not patentably distinct, but are obvious variants of carrying out the methods of the invention.

The Examiner also stated that Applicants are required under 35 USC § 121 to elect a single species from those that are listed in claim 8, *i.e.*, retrovirus, adenovirus, adeno-

associated virus, herpes virus, poliovirus, papillomavirus, or lentivirus. *See* Paper No. 8, page 5.

Accordingly, Applicants hereby provisionally elect the following species: **retrovirus**. Claims 1-3, 5-9 and 13 read on such species. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed.

Applicants assert the right to claim additional species in the event that a generic claim thereto is found to be allowable in accordance with 37 C.F.R. § 1.141(a).

This election of species is made **with** traverse on the ground that the restriction requirement upon which the election of species requirement is based is improper for the reasons set forth above. Applicants further traverse the election of species requirement on the ground that the listed species of viral vectors are not patentably distinct, but are obvious variants of carrying out the methods of the invention.

In view of the foregoing discussion, Applicants respectfully request that both election of species requirements be reconsidered and withdrawn.

Conclusion

Reconsideration and withdrawal of the Restriction Requirement and the Election of Species Requirement, and consideration and allowance of all pending claims, are respectfully requested.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of

time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

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